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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,337	06/15/2001	Klaus Balschat	2565/87	8666

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NEW YORK, NY 10004

EXAMINER

DEAK, LESLIE R

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 08/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/882,337

Applicant(s)

BALSCHAT ET AL.

Examiner

Leslie R. Deak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 June 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Drawings

1. This application has been filed with informal drawings that are acceptable for examination purposes only. FIG 1 is generally crowded with unclear reference characters. Formal drawings will be required when the application is allowed.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-13 and 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 1 introduces the limitations of a dialysis fluid inlet line, a dialysis fluid outlet line, and another inlet line and outlet line. The claim further refers to a mixing point provided in association with "the inlet line." It is unclear which inlet line applicant is referring to at this and subsequent other references to the inlet and outlet lines (e.g., claims 2, 3, 13). Examiner suggests giving each inlet line a unique name and referring to each line by its unique identifier throughout the claims. For purposes of examination, examiner assumes that references to the "inlet line" and the "outlet line" refer to the inlet and outlet lines leading to and from the water source in the proportioning unit.

5. Claim 3 recites the limitation "a cutoff element" that is subsequently located in four places. It is unclear whether applicant is claiming a single element that may be

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placed in any one of the four claimed locations, or four separate cutoff elements.

Examiner, based on the reference to "cutoff elements" in claim 4 has assumed four separate cutoff elements for purposes of examination.

6. Claim 4 recites the limitation that the proportioning unit is "switched." It is unclear what applicant means by the term "switched" in reference to the operation of the proportioning unit.

7. Claim 15 recites the limitation "the setpoint." There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-5 and 7-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,042,784 to Wamsiedler in view of US 4,136,708 to Cosentino et al.

Wamsiedler discloses a dialysis apparatus with a dialyzer 4 with a membrane and a dialysis fluid inlet and outlet (10e, 11e), and a balancing system 13 for maintaining a balance between fresh and spent dialysis fluid (column 4, lines 34-67, column 5, lines 1-23, FIG 1). Connected to the balancing system 13 is a two-chambered balancing device 23 with valves (30, 31, 32, 33) at the inlet and outlet to the device. The inlet and outlet lines of the balancing device are connected to fluid lines, including a dialysis fluid

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source 9 with a degassing pump 9a, which serves as a vent. The dialysis fluid source with its degasser may act as the equalizing chamber claimed by applicant. The dialysis fluid source 9 contains a tubing line 34 that is used as a recirculation line and is fluidly connected to the other fluid tubes in the system. With regard to applicant's claim that the chamber displace one liquid while filling another, such language is merely a statement of intended use, and does not add a patentable limitation to the claims.

Furthermore, while Wamsiedler discloses that the balancing device 23 is for fresh and spent diasylate, it is connected to fluid lines such that it is capable of being filled one chamber at a time. Wamsiedler fails to disclose a water source and multiple dialysis fluid concentrate sources with mixing points and an equalizing chamber. It is well known in the art of blood treatment that dialysis fluid is often mixed from water and multiple concentrates prior to administration to the patient (see, e.g., Cosentino, column 1, lines 10-27). As such, Cosentino discloses a dialysis mixing apparatus with a control circuit, water source 30, at least two dialysis fluid concentrates 10, 20, and various tubing lines, pumps (40, 50, 60) and mixing valves (13, 15, 23, 25, 35) to mix the solutions in any desired proportion, as controlled by the pumps, valves, and control circuit (see FIG 1). The system includes conductivity meters 12 and 22 that are downstream of at least one of the mixing valves. The system further includes a heater 32. The mixed dialysis solution is fed to a holding chamber 70, which may act as an equalizing chamber. The holding chamber 70 has a liquid level indicator in the form of an overflow pipe 77 (column 19, lines 40-45). Therefore, it would have been obvious to one of ordinary skill in the art to add the mixing system as disclosed by Cosentino to the

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balancing chamber dialysis apparatus disclosed by Wamsiedler in order to provide a an appropriate volume and continuous supply of custom-mixed dialysis solution to the patient. Furthermore, the combined device is capable of performing the method as claimed, since the controllers disclosed by Wamsiedler and Cosentino are capable of being programmed to operate the valves, pumps, and warning systems according to any selected algorithm desired by the operator.

10. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,042,784 to Wamsiedler in view of US 4,136,708 to Cosentino et al., in view of US 4,770,769 to Schael. The modified Wamsiedler device discloses the apparatus as claimed. Schael discloses a dosing, mixing, and balancing dialysis apparatus with a balancing system and a dialysis solution mixing and holding chamber 100. The holding chamber 100 comprises a heating and degassing device, as well as a pressure reduction valve 52 therein (column 15, lines 8-17, FIG 8). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide the holding/equalizing chambers disclosed by Cosentino and Wamsiedler with the pressure reduction valve disclosed by Schael in order to provide a continuous supply of mixed dialysis solution at a pressure appropriate for the system, as taught by Schael.

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Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

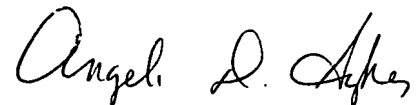
- a. US 4,702,829 Polaschegg et al
 - i. Hemodiafiltration apparatus with mixing areas and balancing units.
- b. US 6,325,774 Bene et al
 - ii. Dialysis apparatus with concentration mixing and control unit.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 703-305-0200. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0873.

lrd
August 9, 2002



ANGELA D. SYKES
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